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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,515	07/08/2003	Alex Gutteridge	674575-2004	9209

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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,515	GUTTERIDGE ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 4, 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 2.

Group II, claim(s) 1, 2, 5-7, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 4.

Group III, claim(s) 1, 3, 8-10, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 6.

Group IV, claim(s) 24-26, 29-31, 37, 48, 50-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 2.

Group V, claim(s) 24, 25, 27, 29-31, 37, 48, 50-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 4.

Group VI, claim(s) 24, 25, 28, 29-31, 37, 48, 50-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 6.

Group VII, claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 2.

Group VIII, claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 4.

Group IX, claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 6.

Group X, claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 2.

Group XI, claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 4.

Group XII, claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 6.

Group XIII, claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising binding a ligand to the polypeptide.

Group XIV, claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 4, or assessing the activity of a polypeptide comprising SEQ ID NO: 4, relative to a control, the method comprising binding a ligand to the polypeptide.

Group XV, claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 6, or assessing the activity of a polypeptide comprising SEQ ID NO: 6, relative to a control, the method comprising binding a ligand to the polypeptide.

Group XVI, claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 2.

Group XVII, claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 4, or assessing the activity of a polypeptide comprising SEQ ID NO: 4, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 4.

Group XVIII, claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 6, or assessing the activity of a polypeptide comprising SEQ ID NO: 6, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 6.

Group XIX, claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2.

Group XX, claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2.

Group XXI, claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2.

Group XXII, claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 2 as an adhesion molecule.

Group XXIII, claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 4 as an adhesion molecule.

Group XXIV, claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 6 as an adhesion molecule.

Group XXV, claim(s) 53-55, drawn to a method of treating disease, comprising administering a polypeptide comprising SEQ ID NO: 2, or a pharmaceutical composition thereof.

Group XXVI, claim(s) 53-55, drawn to a method of treating disease, comprising administering a polypeptide comprising SEQ ID NO: 4, or a pharmaceutical composition thereof.

Group XXVII, claim(s) 53-55, drawn to a method of treating disease, comprising administering a polypeptide comprising SEQ ID NO: 6, or a pharmaceutical composition thereof.

Group XXVIII, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 2, or a pharmaceutical composition thereof.

Group XXIX, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 4, or a pharmaceutical composition thereof.

Group XXX, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 6, or a pharmaceutical composition thereof.

Group XXXI, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 2, or a pharmaceutical composition thereof.

Group XXXII, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 4, or a pharmaceutical composition thereof.

Group XXXIII, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 6, or a pharmaceutical composition thereof.

Group XXXIV, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 2.

Group XXXV, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 4.

Group XXXVI, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 6.

Group XXXVII, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 2.

Group XXXVIII, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 4.

Group XXXIX, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 6.

Group XL, claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 2 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 2.

Group XLI, claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 4 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 4.

Group XLII, claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 6 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 6.

Group XLIII, claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 2.

Group XLIV, claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 4.

Group XLV, claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 6.

Group XLVI, claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 2 with a candidate compound.

Group XLVII, claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 4 with a candidate compound.

Group XLVIII, claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 6 with a candidate compound.

The inventions listed as Groups I-XLVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The requirement of unity of invention is not fulfilled because there is no technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features " means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features.

The inventions of Groups I - XLVIII, do not share a common special technical feature because the technical feature of Group I is a polypeptide comprising SEQ ID NO: 2. This technical feature is not shared by all the groups. Further, SEQ ID NO: 2 is disclosed by Blattner et al. ("The complete genome sequence of Escherichia coli K-12," Science 277(5331):1453-1462, 1997). See also the GenBank record for this polypeptide under GenBank Accession No. AAC74854.

Thus, the technical feature of SEQ ID NO: 2 does not define the invention over the prior art. Because the common special technical feature is not novel, it is clear that the claims of Groups I – XLVIII lack a single common technical feature that defines them over the prior art.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories, in the instant case, the first named product and the first named process of using the product (see 37 CFR 1.475(b)-(d)). Thus, only Groups I and XIII may be considered for unity of invention. Other Groups are drawn to additional processes and products.

Accordingly, a holding of lack of unity of invention is proper.

Further, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) each of the compounds listed in claim 36;

b) each of the diseases listed in claim 46;

c) each of the diseases listed in claim 52;

d) each of the abnormal expression levels listed in claim 62- higher or lower or absent;

e) each of the abnormal expression levels listed in claim 63- higher or lower or absent;

Applicant is required, in reply to this action, to elect a single species in each of groups a) – e) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species,

including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 36, 38, 52, 62 and 63.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents.

For example, claim 36 lists a group of very disparate compounds, e.g., substrates or enzymes or receptors, that increase or decrease the level of expression or activity of a polypeptide. Claims 46 and 52 each list a group of very disparate diseases that are treated by administration of a polypeptide, e.g., restenosis or diabetes. The transgenic animal of claims 62 or 63, or the knock-out animal of claim 62, expresses a supernormal, subnormal or no level of polypeptide.

Because the claimed species are not art-recognized equivalents, a holding of lack of unity of invention is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk/2005-02-16

ROBERT A. WAX
PRIMARY EXAMINER
AU 1653